SAFETY EVALUATION REPORT

for the Mound 1KW Package

Docket 94-16-9516

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√ Office of Licensing, EM-24

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Safety Evaluation Report for the 9516 Packaging SARP, Revisions 7, 7a, 7b, and 7c Docket 94-16-9516

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INTRODUCTION

The Idaho National Laboratory (INL) has prepared for the U.S. Department of Energy (DOE) a series of revisions to the Safety Analysis Report for Packaging (SARP)^[1] for the 9516 Package (referred to herein as the *Mound 1KW SARP*, or the 9516 SARP). The 9516 Packaging is a Type B(U)F packaging system designed for shipping up to approximately 0.5 kW of heat source plutonium (primarily ²³⁸Pu), in various chemical forms and mechanical configurations.

This Safety Evaluation Report (SER) documents the review performed by the Lawrence Livermore National Laboratory (LLNL) staff, at the request of DOE, of the 9516 SARP, Revision 7, Revision 7a, Revision 7b, and Revision 7c. Revision 7 requests adding new extensions of primary containment vessel (PCV) maximum allowable fuel age limits in Appendix 3.6.12. Revision 7a responds to Q1 and Q2 questions and withdraws Appendix 3.6.12. Primarily, it provides clarification and updated figures and tables to establish the available shipment time for Fueled Clads contents for various PCV loading configurations given in Table 3.17 of the SARP. Revision 7b responds to Q3 questions, and provides information on ASME Code compliance issues regarding design and fabrication of the 9516 containment vessels in Appendix 1.3.2. Revision 7c addresses the transfer of responsibility to INL for the use, inspection, maintenance, repair, modification, handling, shipping, storage and cleaning of the 9516 Package, described in Chapter 9, Quality Assurance.

Chapter 1: General Information

This section of the TRR covers the review of the General Information provided in Chapter 1 of the INL submittals.

In chronological order, the following major revisions were made to the 9516 Package documentation:

- 1. The available shipment time for Fueled Clads with one, two, three and four product cans per PCV has been provided in Figures 3.11a, 3.11b, 3.11c, and 3.11d of the SARP. The maximum internal pressures for the PCVs under NCT thermal conditions have been updated in Table 3.17.
- 2. Appendix 1.3.2 of the SARP provides the details of the metrics have been used by ANL-W to quantify the safety requirements of 10 CFR 71. The requirements presented in the SARP are compared to applicable articles and paragraphs of the ASME Boiler and Pressure Vessel Code.
- 3. As part of the closure of the DOE Mound Plant, responsibility for the 9516 Packaging has been transferred to INL. Ongoing use, inspections, maintenance, repair, modifications, handling, shipping, storage and cleaning of the 9516 packaging will be performed under the INL Quality Assurance Plan (QAP).
- 4. For the purpose of compliance with the requirements of the latest revision of 49 CFR 172.310(d), i.e., the revision from October 1, 2004, the name plate description referred to in the SARP will be brought up to date.

Shipment of Fueled Clad in Product Cans under Item 1

The Fueled Clads loading arrangement for Item 1 above will involve any of the following configurations:

- Fueled clads in product cans (1/can, 4 cans per PCV);
- Fueled clads in product cans (1/can, 3 cans per PCV);
- Fueled clads in product cans (2 in one can & 1 per can in 2 cans, 3 cans per PCV);
- Fueled clads in product cans (2/can, 2 cans per PCV); and
- Fueled clads in product cans (2/can, 1 can per PCV).

The results of the transport safety assessment for the subject request are discussed below for the above loading configurations.

Reviews and analyses of the information presented herein were conducted. Due to the similarity to other previously authorized contents, no unusual effects on the packaging were found. The five potential loading configurations, which are discussed in more detail in Chapters 2–9 of this TRR, will require an amendment to the CoC for the 9516 Packaging, prior to shipment.

<u>Transfer of Responsibility for the 9516 Packaging to INL under Items 2 and 3</u> This is discussed in Chapter 9, below.

Updating of Nameplate Information under Item 4

To be implemented as a new requirement in the CoC, prior to shipment. (See Section 8, below.)

1.1 Findings

Based on the review of the statements and representations provided in the SARP, and, in particular, based on the review of the statements and representations provided in SARP Revision 7a, the staff has concluded that the request has been adequately described to meet the requirements of 10 CFR 71.

1.2 Conditions of Approval

Although the staff has concluded that no additional conditions of approval need to be added to the existing Certificate of Compliance $(CoC)^{[6]}$ for the approval of this request, specific sections of the CoC were modified for clarification. These modifications are included in the discussion of Chapters 2–8 below.

Chapter 2: Structural Evaluation

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the assessment of the Structural Evaluation information provided in Chapter 2 of the INL submittals. The submittals do not indicate any change of the structural design of the package. Revision 7, 7a, 7b, and 7c of the SARP provide few additional

details but essentially the same information as that in Revision 6b, which has been reviewed and accepted as the basis for the current DOE CoC for the package.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

2.1 Findings

The Structural review confirmed that the text and sketches describing the structural design features are consistent with the engineering drawings and the models used in the structural evaluation.

The criteria for design of the package are in accordance with 10 CFR 71,^[7] 49 CFR Parts 173 through 178,^[8] and IAEA Safety Series No. 6.^[9] The criteria for design of the package are also in accord with the American Society of Mechanical Engineers' (ASME) Boiler and Pressure Vessel Code (B&PVC) (the Code).^[10] Particularly, the design of the containment vessels has been shown to be based on ASME Code Section III, Division I, Subsection NB, and Regulatory Guides 7.6^[11] and 7.8.^[12]

The structural section of the SARP was reviewed to determine that the 9516 Package was designed in a manner that will assure compliance with the applicable performance requirements of 10 CFR Part 71 and IAEA Safety Series 6 for shipment under normal conditions of transport (NCT), hypothetical accident conditions (HAC), and the applicable design requirements of the ASME B&PVC, Section III. The scope of the review covered the structural design, the weights and centers of gravity, the mechanical properties of the materials, the general standards for all packages, the lifting and tie-down standards for all packages, the structural evaluation for normal conditions of transport, the structural evaluation for hypothetical accident conditions, and supportive information or documentation. For normal conditions of transport, PCV and SCV wall temperatures were limited to 426.7° (800°F). The maximum weight of the SCV and its contents was established at 32.6 kg (72 lb).

Basis for acceptance in the review was conformance with established guidelines and criteria. The review of the 9516 Package structural design indicates that, under normal conditions of transport and hypothetical accident conditions, a package loaded with eight product cans containing PuO₂ powder fuel at a weight equivalent to 500 watts total heat is in compliance with the applicable performance requirements of 10 CFR Part 71 and the applicable design requirements of the ASME B&PVC, Section III. Furthermore, there are no adverse structural effects on the containment, shielding, or criticality functions of the package.

Since all other contents of the package have similar total heat, total mass, and distribution of mass and heat, the 9516 Package with these other contents will also be in compliance with 10 CFR part 71, 49 CFR part 173, and IAEA Safety Series 6 requirements.

The staff concludes that the protective features provided in the design of the 9516 Package conform to applicable regulations, regulatory guides, and industry standards, and are acceptable.

2.2 Conditions of Approval

Based on the review of the statements and representations in the INL submittals, the staff has concluded that the package design has been adequately described to meet the requirements of 10 CFR 71. The staff has also concluded that no additional structurally-related conditions of approval need to be added to the existing $CoC^{[6]}$ for the approval of these revisions.

Chapter 3: Thermal Evaluation

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the assessment of the Thermal Evaluation information provided in Chapter 3 of the submittals.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

The available shipment time for Fueled Clad with one, two, three, and four product cans per PCV has been provided in Figures 3.11a, 3.11b, 3.11c and 3.11d of the SARP. The maximum internal pressures for the PCVs under NCT thermal conditions have been updated in Table 3.17 of the SARP. The information provided in the figures provides the loading requirements for the five potential loading configurations, as a function of the internal pressures available shipment times, for fueled clad and heat content in each PCV.

3.1 Findings

Based on the review of the statements and representations in the INL submittals, the staff has concluded that the thermal design of the 9516 Package configurations have been adequately described to meet the requirements of 10 CFR 71.

3.2 Conditions of Approval

Based on the findings described above, the staff has concluded the following will be added to the CoC: The information in Figures 3.11a, 3.11b, 3.11c and 3.11d. and Table 3.17 of the SARP provides the basic loading requirements for the five potential loading configurations, as a function of the internal pressures available shipment times, for fueled clad and heat content in each PCV.

Chapter 4: Containment Evaluation

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the assessment of the Containment Evaluation information provided in Chapter 4 of the submittals.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

4.1 Findings

The 9516 Package was originally certified under the requirements of 10 CFR 71 (1983), [13] and later recertified under the requirements of 10 CFR 71 (1996). As a consequence, the 9516 Package includes a double-containment system, as was required by the earlier regulatory requirements for plutonium oxide shipments. Since the applicant has not requested any relief from the double-containment requirements of 10 CFR 71.63 (1983) and/or 10 CFR 71.63 (1996), the older, double-containment requirements for plutonium oxide shipments are still applicable. Since the addition of the newer payload configurations does nothing to change the situation, the staff has concluded that the containment design has been adequately described to meet the requirements of 10 CFR 71.

4.2 Conditions of Approval

Based on the review of the statements and representations in the INL submittals, the staff has concluded that the package design has been adequately described to meet the requirements of 10 CFR 71. The staff has, therefore, concluded that no additional containment-related conditions of approval need to be added to the existing CoC^[6] for the approval of these revisions.

Chapter 5: Shielding Evaluation

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the review of the Shielding Evaluation information provided in Chapter 5 of the submittals.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

5.1 Findings

The shielding evaluations for the Fueled Clads and Russian contents are bound by previous analyses performed for 9516 SARP.

Based on the review of the statements and representations in the INL submittal, the staff has concluded that the shielding evaluation of the 9516 Package configuration has been adequately described to meet the requirements of 10 CFR 71.

5.2 Conditions of Approval

Based on the review of the statements and representations in the INL submittals, the staff has concluded that the package design has been adequately described to meet the requirements of 10 CFR 71. The staff has, therefore, concluded that no additional shielding-related conditions of approval need to be added to the existing CoC^[6] for the approval of these revisions.

Chapter 6: Criticality Evaluation

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the review of the Criticality Evaluation information provided in Chapter 6 of the submittals.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

6.1 Findings

The criticality evaluations for the Fueled Clads and Russian contents are bound by previous analyses performed for the GPHS modules.

Based on the review of the statements and representations in the INL submittal, the staff has concluded that the criticality evaluation of the 9516 Package configuration has been adequately described to meet the requirements of 10 CFR 71. The criticality safety index is 0.

6.2 Conditions of Approval

Based on the review of the statements and representations in the INL submittals, the staff has concluded that the package design has been adequately described to meet the requirements of 10 CFR 71. The staff has, therefore, concluded that no additional criticality-related conditions of approval need to be added to the existing CoC^[6] for the approval of these revisions.

Chapter 7: Operating Procedures

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the review of the Operating Procedures information provided in Chapter 7 of the submittals.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

Shipment of fueled clad assemblies

The methods used to calculate the maximum internal pressures and the maximum thermal stresses for the primary containment vessels, the secondary containment vessels, and the cask are described in Section 3.4.4 of Reference [3]. The results of these calculations are summarized in Table 3.17 of Reference [3], which includes the time to reach the maximum allowable pressure for the loading arrangements for the following five potential loading configurations:

- Fueled clads in product cans (1/can, 4 cans per PCV);
- Fueled clads in product cans (1/can, 3 cans per PCV);
- Fueled-clads in product cans (2 in one can and 1 per can in 2 cans, 3 cans per PCV);
- Fueled clads in product cans (2/can, 2 cans per PCV); and

• Fueled clads in product cans (2/can, 1 can per PCV).

The methodology described is basically the same methodology that is used to describe similar contents for the 5320 Package. When combined with the appropriate additional steps in the Operating Procedures, the methodology described has already been approved for the shipment of similar contents for the 5320 Package. All Package.

The information that summarizes the loading requirements for the shipment of fueled clad assemblies over the age of two years since pressing is presented graphically in Figures 3.11a, 3.11b, 3.11c, and 3.11d of the SARP. Supplemental information is also summarized in Table 3.17 of the SARP, which was also from Reference [3].

The information provided in the Figures provides the loading requirements for the five potential loading configurations, as a function of the internal pressures available shipment times, for fueled clads and heat content in each PCV. When supplemented with the more specific information provided in Table 3-1, this information should be included in an amendment to the existing CoC, i.e., Reference [6].

7.1 Findings

Based on the review of the statements and representations provided in References 1–4, and, in particular, based on the review of the statements and representations provided in Sections 3.4.4 and 3.4.5 (for NCT) and Sections 3.5.4 and 3.5.5 (for HAC) of the Revised SARP application, i.e., Reference 3, the staff has concluded that the request has been adequately described to meet the requirements of 10 CFR 71.

7.2 Conditions of Approval

Based on the findings described above, the staff has concluded that the information provided in Figures 3.11a, 3.11b, 3.11c, and 3.11d of the SARP provides the basic loading requirements for the five potential loading configurations, as a function of the internal pressures and available shipment times, for fueled clads and heat content, in each PCV. When supplemented with the content-specific information provided in Table 3.17 of the SARP, the staff has concluded that this information should be included as a modification to the Conditions of Approval for the CoC for the 9516 Package.

Chapter 8: Acceptance Tests and Maintenance Program

This section addresses the staff's findings regarding the review of the INL submittals, i.e., Revisions 7, 7a, 7b and 7c of the 9516 SARP, noted herein as References [2], [3], [4], and [5], respectively. This section covers the review of the Acceptance Tests and Maintenance Program information provided in Chapter 8 of the submittals.

Details of the items reviewed are listed above in the General Information Section, i.e., Chapter 1. The results of the review are discussed below.

Updating of Nameplate Information

To be implemented as a new requirement in a letter amendment to the CoC, prior to shipment.

8.1 Findings

For purposes of compliance with the requirements of the October 1, 2004 revision to 49 CFR 172.310(d), the name plate description referred to in Section 8.1 of the Revised SARP application, i.e., Reference 3, should be brought up to date.

8.2 Conditions of Approval

For purposes of compliance with the requirements of the October 1, 2004 revision to 49 CFR 172.310(d), the nameplate description referred to in Section 8.1 of the Revised SARP application should be brought up to date, prior to the first shipment. An additional requirement to bring the nameplate description up to date has been added to the CoC approval document.

Chapter 9: Quality Assurance

Revisions 7, 7a, 7b and 7c of the 9516 SARP describes the applicant's (Idaho National Laboratory [INL]) quality assurance (QA) program for design, procurement, fabrication, handling, shipping, storage, cleaning, assembly, operation, inspection, testing, maintenance, repair, modification, and use of the 9516 Package.

The QA review verifies that the applicant's QA program described in Chapter 9 in the submittal of Revision 7c of the 9516 SARP meets the regulatory requirements of 10 CFR 71 Subparts D, F, G, and H listed in Section 9.2 below.

9.1 Elements Reviewed

The following elements of the applicant's QA program were reviewed. Details of the review are provided in Section 9.3 below.

- 9.1.1 Description of Applicant's QA Program
 - Scope
 - QA Program Documentation and Approval
 - Summary of 18 Quality Assurance requirements of 10 CFR 71, Subpart H.
 - Cross-Referencing Matrix of 10 CFR 71, Subpart H to the Applicant's QA Program/Procedures
- 9.1.2 Applicant's QA Requirements
 - Graded Approach for Structures, Systems, and Components Important to Safety
 - Applicant's QA Criteria and Package Activities

9.2 Regulatory Requirements

10 CFR 71 requirements applicable to the QA review are as follows:

• The applicant must describe the quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the package. [§71.31(a)(3), §71.37]

- The applicant must identify established codes and standards proposed for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of any codes and standards, the application must describe the basis and rationale used to formulate the package quality assurance program. [§71.31(c)]
- Package activities must be in compliance with the quality assurance requirements of Subpart H (§71.101-§71.137). A graded approach is acceptable. [§71.81, §71.101(b)]
- Sufficient written records must be maintained to furnish evidence of the quality of the packaging. These records include results of the determinations required by §71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of maintenance, modification, and repair activities; and other information identified in §71.91(c). Records must be retained for three years after the life of the packaging. [§71.91(c)]
- Records identified in §71.91(a) must be retained for three years after shipment of radioactive material. [§71.91(a)]
- Records must be available for inspection. Records are valid only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. [§71.91(b)]
- Any significant reduction in the effectiveness of a packaging during use must be reported to the certifying authority. [§71.95(a)]
- Details of any defects with safety significance in a package after first use, with the means employed to repair the defects and prevent their reoccurrence, must be reported. [§71.95(b)]
- Instances in which a shipment does not comply with the conditions of approval in the certificate of compliance must be reported to the certifying authority. [§71.95(c)]

9.3 Review Procedures

This section details the review of the elements listed in Section 9.1 of this TRR.

9.3.1 Description of Applicant's QA Program

9.3.1.1 Purpose and Scope

The Purpose and Scope of Chapter 9, Quality Assurance, of the SARP were reviewed to confirm that Chapter 9 explicitly states the applicant's QA Program complies with 10 CFR 71, Subpart H, and is applied to package-related activities including procurement activities consistent with the applicable regulatory requirements. Idaho National laboratory became responsible for the 9516 Packaging in February 2005 at which time Argonne National Laboratory—West (ANL-W) became part of INL. Section 9.0 states that Chapter 9 discusses the INL QA requirements for the design, fabrication, assembly, acceptance testing, procurement, use, periodic inspection, weld examination, maintenance, repair, modification, handling, shipping, storage, and cleaning of the 9516 Package that comply with 10 CFR 71, Subpart H. Section 9.0 further explains that per the approval of DOE-NE, INL will continue to use the previous ANL-W QA program, procedures, and documents listed in the Chapter 9 reference list. Section 9.2.1 states that INL is in the process of replacing the previous ANL-W procedures (AWPs) with INL laboratory wide procedures (LWPs).

Section 9.1 and Figure 9-1 of the SARP describe the applicant's organization, including the QA groups and their responsibilities relative to management and implementation the QA Program. The applicant purchases 9516 Package fabrication services from suppliers that have been evaluated and approved to meet the applicable requirements of 10 CFR 71, Subpart H.

9.3.1.2 Program Documentation and Approval

Section 9.0 of the SARP states that INL will use the previous ANL-W QA Program (QAP), W0001-0929-QM, Revision 10, that describes the overall framework within which the INL quality assurance activities for the 9516 Package are implemented. Section 9.2 describes that the ANL-W QAP, referred to as the INL QAP, meets the requirements of 10 CFR 830.120, [16] DOE Order 414.1B, [17] and the provisions of NQA-1-2000. [18]

Quality assurance activities for the 9516 Package operate within the scope of the previous ANL-W Radioisotope Power System/Heat Source (RPS/HS) QA Program Plan (QAPP) that is referred to as the INL RPS/HS QAPP. The INL RPS/HS QAPP is implemented with the use of procedures that detail specific requirements in the INL QAP. Section 9.0 explains that per the approval of DOE-NE, INL will continue to use the previous ANL-W QA program, procedures, and documents listed in the Chapter 9 reference list that are in the process of being replaced with equivalent INL LWPs. Section 9.19 lists the current QA implementing procedures that consist of a combination of the previous ANL-W AWPs and new INL LWPs.

As required by §71.31(a)(3) and §71.37, Sections 9.1.1 and 9.2 of the SARP identify that the INL-W RPS/HS QAPP complies with 10 CFR 71, Subpart H (in addition to the INL-W QAP, DOE Order 460.2A, DOE Order 460.1B, and NQA-1-2000 [18]). Idaho National Laboratory purchases 9516 Package fabrication services from suppliers that have been evaluated and approved to meet the applicable requirements of 10 CFR 71, Subpart H. Idaho National Laboratory uses NQA-1-2000 as a quality management standard for meeting the requirements of 10 CFR 71, Subpart H.

Additional information on the hierarchy and relationship of requirements documents and the relevant INL QA plans and implementing procedures is provided in Figure 9-2. The current revision and date of the applicable INL QA Plans are provided in the References section in Chapter 9.

9.3.1.3 Summary of 18 Quality Assurance Requirements from 10 CFR 71, Subpart H Table 9-1 lists and summarizes the INL-W RPS/HS QAPP sections that implement the 18 quality assurance requirements in 10 CFR 71, Subpart H.

9.3.1.4 Cross-Referencing Matrix

Table 9-1 provides a cross-referencing matrix that links the INL-W RPS/HS QAPP sections to the corresponding QA requirements in 10 CFR 71, Subpart H.

9.3.2 Applicant QA Requirements

9.3.2.1 Graded Approach for Structures, Systems, and Components Important to Safety
Section 9.2.3 was reviewed to verify it describes the graded application of the ANL-W RPS/HS
QAPP to the 9516 Package structures, systems, and components (SSCs), including software that
is important to safety, consistent with the requirements in §71.81 and §71.101(b), and the
guidance in Reg. Guide 7.10. [21] Safety-related "Q" package components are categorized as
Levels A, B, or C, with Level A items having the largest impact on safety. Table 9-4 of the
SARP identifies the graded level of QA controls that apply to each of the INL QA Levels. The
9516 Package SSCs and their QA levels are provided in Table 9-2. Table 9-3 correlates the INL
QA Levels A, B, and C for the 9516 Package to the corresponding safety designations in
Regulatory Guide 7.10.

The review verified the SSCs listed in Table 9-2 are consistent with information presented in the packaging drawings. The INL QA Levels assigned to the SSCs are properly justified based on their definition, the package type, and the safety function of each SSC.

Section 9.2.3 also explains that all software is to be assessed for and receive the appropriate amount of QA per the graded approach described in Section 4.0 of AWP 4.2. Commercial grade hardware and software can be dedicated (i.e., qualified) for safety-related applications in accordance with the controls described in AWP 2.9, Software Design Control which references AWP 4.9, Software QA.

9.3.2.2 Applicant's QA Criteria and Package Activities

Chapter 9 of the SARP was reviewed to verify it adequately described the QA controls and their application consistent with the requirements in §71.31(a)(3) and §71.37. Chapter 9 describes how the QA controls in each section of the INL-W RPS/HS QAPP (listed in Table 9-1) are applied by INL to the design, procurement, fabrication, handling, shipping, storage, cleaning, assembly, welding, operation, inspection, testing, maintenance, repair, modification, and use of the 9516 Package. Chapter 9 also includes INL's provisions for implementing additional QA requirements of 10 CFR 71 that are listed in Section 9.2 above.

The graded approach described in Section 9.3.2.1 above is used by INL to selectively apply the QA controls to package SSCs and software based on their importance to safety. Each section in Chapter 9 also references the applicable QA implementing procedures that will be used by INL.

Section 9.3 describes the graded design controls for software and hardware. Design modifications to the 9516 Package will be evaluated using the unreviewed safety evaluation process, and will require SARP revisions and approvals by the DOE Office of Nuclear Energy (DOE/NE-50) and DOE Headquarters Packaging Certification Office prior to implementation.

Sections 9.4 and 9.7 collectively identify the graded controls for procurement documents and purchased materials and services including package design, SARP preparation, and packaging fabrication. These provisions ensure that procured items and services affecting quality of the 9516 Package meet appropriate design basis, technical and quality assurance requirements. Procurement documents and changes must be reviewed and approved prior to issue.

Section 9.6 identifies documents that are controlled to ensure correct documents including instructions and procedures (described in Section 9.5) are used and that records requirements are met. Controlled documents include operating procedures (SARP Chapter 7), procurement documents (SARP Section 9.7), and the inspection, testing, and maintenance procedures (SARP Chapter 8 and Section 9.10).

Section 9.9 describes the INL controls for special processes, such as welding of the containment vessels, and nondestructive examination of the package during fabrication, use, and maintenance. ANL-W procedure AWP 2.4 establishes the requirements for qualifying special process procedures, equipment, and personnel in accordance with applicable codes, standards, and specifications.

Sections 9.15 and 9.16 collectively describe the controls for documenting, resolving, and preventing the recurrence of package-related nonconformances identified by package users or suppliers. Section 9.15 includes provisions for obtaining INL Material Review Board approval of nonconformance disposition and reporting package defects that significantly reduce safety performance of the package to the DOE Certifying Authority, in accordance with §71.95.

Section 9.17 summarizes the provisions for ensuring sufficient written records are maintained to furnish evidence of the quality of the 9516 Package. The records and their retention requirements, identified in Section 9.17 and Table 9-5, are consistent with the requirements specified in §71.85, §71.91(a), and §71.91(c).

Section 9.18 describes the INL system for independent assessments that is documented in Section 10 of the RPS/HS QAPP.

9.3.3 Appendix

Chapter 9 in the 9516 SARP includes a list of references and definitions of terms and a list of acronyms commonly used in the Chapter 9.

9.4 Evaluation Findings

9.4.1 Findings

Based on review of the statements and representations in the SARP, the staff concludes that the applicant's quality assurance program has been adequately described and meets the quality assurance requirements specified in 10 CFR 71. The SSCs listed in Table 9-2 are consistent with information presented in the packaging drawings. The applicant's quality assurance program is adequate to assure that the package is designed, fabricated, assembled, tested, used, maintained, modified, and repaired in a manner consistent with its evaluation.

9.4.2 Conditions of Approval

Based on the findings described above, the staff concludes that the CoC should include the Chapter 9 requirements, in particular the packaging-specific Quality Assurance requirements.

- [1] Safety Analysis Report for Packaging (SARP) for the Mound 9516 Type B Shipping Package, MLM-MU-91-64-001, Revision 6b, 7/94.
- [2] Safety Analysis Report for Packaging (SARP) for the Mound 9516 Type B Shipping Package, MLM-MU-91-64-001, Revision 7, 3/96.
- [3] Safety Analysis Report for Packaging (SARP) for the Mound 9516 Type B Shipping Package, MLM-MU-91-64-001, Revision 7a, 6/27/03.
- [4] Safety Analysis Report for Packaging (SARP) for the Mound 9516 Type B Shipping Package, MLM-MU-91-64-001, Revision 7b, 5/04.
- [5] Safety Analysis Report for Packaging (SARP) for the Mound 9516 Type B Shipping Package, MLM-MU-91-64-001, Revision 7c, 2/15/06.
- [6] U.S. Department of Energy Certificate of Compliance for USA/9516/B(U)F-85 (DOE), Revision 10, November 25, 2005.
- [7] Nuclear Regulatory Commission, 10 CFR Part 71, Compatibility with International Atomic Energy Agency (IAEA), Final Rule, 60 F.R. 50248, pp. 50248–50289, September 28, 1995, as amended.
- [8] Department of Transportation, 49 CFR Parts, 171, 172, 173, 174, 175, 176, 177, and 178, Hazardous Materials Transportation Regulations; Compatibility with Regulations of the International Atomic Energy Agency, Final Rule, 60 F.R. 50292, pp. 50292–50336, September 28, 1995, as amended.
- [9] International Atomic Energy Agency, Safety Series No. 6, 1985, as amended, 1990, Regulations for Safe Transport of Radioactive Material, IAEA, Vienna, 1990.
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